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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/480,908	06/07/1995	GARY K. MICHELSON	101.0053-00000	9745
22882	7590	05/01/2007	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			BROWN, MICHAEL A	
ART UNIT		PAPER NUMBER		
3772				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

(1)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	08/480,908	MICHELSON, GARY K.
	<b>Examiner</b>	<b>Art Unit</b>
	Michael Brown	3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 February 2007.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9, 11-25, 28-145, 148-156, 158-162, 164-168, 170-174, 176-180, 182-192 and 195-197 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date ALL.IOS
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**Continuation of Disposition of Claims:** Claims pending in the application are 1-9,11-25,28-145,148-156,158-162,164-168,170-174,176-180,182-192 and 195-197.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 11-25, 28-31, 33-75, 77-153, 158-159, 164-165, 170-171, 176-177, and 182-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godefroy in view of Kulich (5,458,638).

Godefroy discloses in figures 1-9 an interbody spinal implant comprising a body (the body in fig. 1), having an insertion end 3, a trailing end (at 22), including a thread (13, 14), the body is substantially frusto-conical shaped (fig. 1), the body is substantially cylindrical shaped (fig. 1), the leading end 3 is larger than the trailing end (fig. 1), the implant includes a bone ingrowth material, fusion promoting material 100, the body has openings (9, 10), the thread radius is variable (because of the shape of the body), the body is a porous material (having openings), an internal chamber (the inside of the body), a wall 2 surrounding the inner chamber, the wall has openings ((9, 10), an engagement means (col. 3, lines 45-47), at least one truncated side 6, that forms a planar surface (fig. 4), the body has an upper portion (fig. 1) and a lower portion (fig. 1), a second truncated side 5, the body is made of a material stronger than bone (metal). Godefroy discloses an implant comprising a pair of arcuate surfaces (the surfaces of 2 and 4) and a pair of planar surface (the surfaces of (5, 6). However, it could be argued

that Godefroy doesn't disclose threads on the body, a means for closing the body, the body having wells having partial walls, a thread being on the truncated wall. Kuslich teaches in figures 2a a tapered spinal implant comprising threads (26, 28) along truncated walls (fig. 2), a means (18, 20) for closing the implant and the body having wells (the wells are formed between the threads). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the spinal implant disclosed by Godefroy could be fabricated with threads along the truncated side walls, means for closing body, wells on the body and threads along the entire walls of the truncated implant. The threads on the truncated planar walls would assist in holding the device in place. The means for closing the body would prevent bone chips or bone grafts from coming out of the implant. The wells would allow bone to grow around the implant. The thread on the outside of the body could be constant or vary. The length, diameter, the insertion end and the trailing end could be within the ranges recited in the claims, because these dimensions are not critical. As for claim 183, Kuslich teaches a continuous thread extending along a majority of the length. As for claim 186, Godefroy discloses a pair of flat sides (5, 6) that are uninterrupted by the threads .

Claims 8, 32, 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Ray (4,904,260). Ray teaches in figures 1 a spinal implant that can be made of a bioabsorbable material (col. 5, lines 54-58). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the implant disclosed by Godefroy and taught

by Kuslich could be fabricated of a bioabsorbable material as taught by Ray in order to allow the implant to absorb into the body after the healing process is completed.

Claims 154-156, 160-162, 166-168, 172-174, 178-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Nies, along with Brekke.

Nies teaches a spinal procedure comprising bone promoting substances that include hydroxyapatite (col. 4, lines 10-15 or hydroxyapatite tricalcium phosphate (col. 3, lines 65-67). Brekke teaches using b one morphogenic protein to enhance bone growth. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the bone promoting substances as taught by Nies and Brekke could be substituted for the bone promoting substances disclosed by Godefroy and taught by Kuslich because either substance could be used to create fusion between the spinal implant and the vertebrae:

#### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 195-197 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 154, 169 and 195 of copending Application No.

10/047,545. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed February 13, 2007 have been fully considered but they are not persuasive. Applicant argues that Godefroy doesn't disclose an implant having a body including threads or the body being substantially cylindrical shaped. However, the teeth (13, 14) are used to cut into the bone and hold the implant in place (thus making them threads) and the body isn't cylindrical, but it is substantially cylindrical (more cylindrical than any other shape). The body is frustoconical shaped. However, the drawings still show a substantially (not cylindrical but substantially cylindrical shaped) cylindrical body. Applicant argues that the radius of the thread on Godefroy isn't variable. However, the thread is variable because it is small on one end and larger on the other end of the implant. Applicant argues that Kuslich doesn't teach threads along truncated walls. However, the body of the implant in figure 2a of Kuslich is truncated. Thus, making the walls truncated. There are threads on the walls. Thus, providing threads along truncated walls. Applicant argues that there is no motivation for combining the disclosure of Godefroy with the disclosure of Kuslich. Applicant also argues that the motivational statement doesn't state why a person of ordinary skill in the art would seek to replace annular ribs of Godefroy with the threads of Kuslich. As set forth in the motivational statement: One of ordinary skill in the art would have incorporated the threads on the truncated wall to hold the implant in place in the

vertebrae. The threads on Kuslich could be substituted for the threads on Godefroy in order to have threads along the entire body of the implant. The threads on both implants are interchangeable. Both set of threads are used to hold the implant in place in the vertebrae. Applicant argues that substituting the threads on Kuslich for the threads on Godefroy would render the device unsuitable for its intended use. However, any threads on a spinal implant are used to hold the implant in place. Thus, it isn't clear how the intended use would be changed via the substituting of one set of threads for another set of threads. Applicant argues that placing a thread on the truncated sides of Godefroy implant adds material to the implant. However, adding the threads to the flat side would allow the flat portion to be held firmly within the vertebrae. It isn't clear how wanting to reduce the material would prevent one of ordinary skill from placing the threads on the flat sides of Godefroy. Applicant argues that claims 8, 32, 76, 154-156, 160-162, 166-168, 172-174 and 178-180 depend from allowed claims. However, no claims in this case have been indicated as allowable.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown  
April 29, 2007



MICHAEL A. BROWN  
PRIMARY EXAMINER